

NASA Standard Measures Overview

March 2008



Bed Rest Project Background

Due to the limited in-flight resources available for human physiological research in the foreseeable future, NASA has increased its reliance on head-down bed rest.



NASA has created the Bed Rest Project at the Johnson Space Center, which is implemented on the 6th floor of the Children's Hospital at UTMB. It has been conducted for three years.

The overall objective of the Project is to use bed rest to develop and evaluate countermeasures for the ill effects of space flight before flight resources are requested for refinement and final testing.



Human Test Subject Facility

- Assumes responsibility for recruiting and screening all test subjects for the Flight Analogs Project's local studies.
 - 2 full-time physicians; 1 part-time physician
 - 2 full-time nurses; 3 part-time nurses
 - 1 administrative assistant
- Advertisements are run in newspapers and on the radio and television in the Houston and Galveston areas.
- Web site in place to aid in recruitment.
- If recruitment lags, will advertise in Dallas, Austin, San Antonio and New Orleans.



Human Test Subject Facility

- Travel budget is available for out-of-town subjects.
- Perform all screening physicals for the Flight Analogs Project, according to standard criteria (in conjunction with the JSC Clinical Lab and employee clinic).
- Physicians also serve as test monitors, when required.



Subject Recruitment Criteria

- **Healthy male and female adults, aged 25 – 55 years.**
- **Subjects are pre-screened via telephone by HTSF nursing staff.**
- **Required to pass a modified Air Force Class III Physical examination, or equivalent, within 1 year prior to start of study, must be capable of giving informed consent and pass a psychological screen.**
- **Blood chemistry testing occurs**
- **Hematology profiles are performed**
- **After physical screenings, subject candidates are tested and interviewed by a psychologist for assessments of the subjects' ability to complete all aspects of the study.**



Subject Exclusionary Criteria

- **Hypertension**
- **Electrocardiogram abnormalities**
- **Require medications that may interfere with the interpretation of the results**
- **Recent sub-standard nutritional status**
- **Metal implants which could interfere with MRI imaging**
- **History of thyroid dysfunction, renal stones, mental illness, gastroesophageal reflux disease, cardiovascular disease, musculoskeletal or sensorimotor dysfunction**
- **Smoking within six months prior to the start of the study**
- **Personal or family history of thrombosis**
- **BMI outside of 21-30**
- **Abnormal blood or urine chemistries**
- **Cannot clear a criminal background check**
- **Females must have regular menses, may not use hormonal contraceptives and cannot be pregnant**



Standardized Conditions of Bed Rest

- **Duration:** 90 days
- **Bed Position:** 6 degrees head down tilt, continuous for the duration of the study
- **Environmental:** 70-74 degrees F.
- **Light/Dark Cycle:** lights on 0600, lights out 2200 (no napping)
- **Daily Measurements:**
 - Blood Pressure, Heart Rate, Respiratory Rate, Temperature
 - Body Weight
 - Fluid Intake and Output
- **Monitoring:** by Subject Monitors in person or via in room camera 24 hours a day
- **Stretching Regimen:** twice daily
- **Physiotherapy:** every other day during bed rest and every day for the first seven days post bed rest



Standardized Diet

- **Isocaloric diet** based on the NASA space flight nutritional requirements; caloric intake 35.7 kcal/kg body wt (2500 calories/70 kg subject)
- **Fluid intake** of 28.5 ml/kg body wt (2000 ml/70 kg subject)
- **Carbohydrate:Fat:Protein ratio – 55:30:15**
 - phosphorus – 1400 mg/day
 - sodium – 2 mmol/kg/day
 - potassium – 1.3 mmol/kg/day
 - calcium – 1000 mg/day
- **No caffeine, cocoa, chocolate, tea or herbal beverage**
- **All food must be consumed**
- **Caloric intake adjusted to maintain body weight**
- **Iron supplementation is provided for all female subjects and for male subjects with a low ferritin at study entry**





Life Sciences Research Laboratories

- These are the research laboratories within the Human Adaptation and Countermeasures Division at the Johnson Space Center.
- Hold responsibility for collecting flight medical requirements on crew members before and after spaceflight.
- Hold responsibility for collecting Standard Measures on bed rest subjects.
- These laboratories are paid by the Flight Analogs Project to collect these measures. They will provide the Project with the data, which will be shared with the science investigators.



Standard Measures

- Provide a basis to compare results between bed rest investigations and to compare results of bed rest and flight studies.
- Provide a detailed description of the physiologic responses to bed rest in humans across all appropriate disciplines
- Help to determine predictive characteristics of susceptibility of subpopulations to bed rest and/or spaceflight.
- Help to determine gender differences in bed rest and/or spaceflight.
- Provide opportunities for collaboration.



Standard Measures

- **Provide a basis to compare results between bed rest investigations and to compare results of bed rest and flight studies.**
- **Determine predictive characteristics of susceptibility of subpopulations to bed rest and/or spaceflight.**
- **Provide a detailed description of the physiologic responses to bed rest in humans across all appropriate disciplines.**
- **Describe the differences between men and women in the responses to bed rest.**
- **Collect data for all NASA/NSBRI-funded bed rest subjects to the greatest extent possible.**
- **Integrate with science investigation requirements on a non-interfering basis; providing multi-disciplinary ancillary data to individual investigators.**
- **Part of the medical monitoring of subjects.**
- **Provide opportunities for collaboration.**
- **Will be re-assessed and updated periodically.**



Standard Measures from Flight Medical Requirements

- **Neurocognitive Assessment (WinSCAT) MR085L**
- **Bone Mineral Densitometry (DXA) MR035L**
- **Clinical Laboratory Assessment (Blood Draw and Urinalysis) MR010L**
- **Clinical Nutritional Assessment (Nutrition) MR016L**
- **Isokinetic Muscle Function Testing (Cybex) MR079L**
- **Aerobic Capacity - Cycle Ergometry (Cycle) MR080L**
- **Functional Neurological Assessment (Posture) MR042L**
- **Functional Fitness (MR078L)**
- **Operational Tilt Test (MR001L)**



Additional Standard Measures for the Flight Analogs Project

- **Gastrointestinal Function**
- **Cardiovascular Assessment**
 - **Cardiac Function**
 - **Neuroendocrine and Cardiovascular Responses to Tilt**
 - **Plasma Volume**
- **Bone mass and structure via pQCT**
- **Functional Stretch Reflex (FSR) Test**
- **Immune Function Assessments**
 - **Biochemical and Psychological Stress Measures**
 - **Virus-Specific T-Lymphocyte Immunocompetence**
 - **Latent Herpesvirus Reactivation**



Standard Measures

Neurocognitive Assessment (MR085L)

Cognitive function measured using the same neurocognitive assessment tool required for crewmembers aboard long-duration space flight missions. Sustained concentration, Verbal working memory, attention, short-term memory testing, spatial processing, and math skills will be assessed



Bone Mineral Densitometry (MR035L)

Bone mineral density changes associated with bed rest will be assessed using the Dual Energy X-Ray Absorptiometry (DEXA). This test is required of all long duration crewmembers. Whole body, hip, lumbar spine, heel, and wrist will be measured.



Standard Measures

Clinical Laboratory Assessment (MR010L)

Hematology, clinical biochemistry, routine Urines involving venipuncture blood draws and urinalysis will be collected and analyzed.



Clinical Nutritional Assessment (MR016L)



Nutritional analysis and detection of bone resorption and bone formation rates is measured by blood samples and dietary intake with anthropometric information. Circulating bone- and calcium-regulatory factors will be assessed in serum samples. Markers of bone resorption, including collagen crosslinks, urinary calcium, urinary phosphorus, and urinary creatinine will be determined from urine samples.



Standard Measures

Isokinetic Testing (MR079L)



Assessment of muscle strength and endurance testing of long-duration astronauts will be repeated on all bed rest subjects. Testing will occur on the knee, ankle, and back muscles.

Cycle Ergometry (MR080L)

Aerobic test on a cycle ergometer to determine aerobic capacity. Oxygen uptake will be measured during the test with the use of a metabolic gas analysis system .





Standard Measures

Functional Neurological Assessment MR042L

- **Monitors critical aspects of degradation and recovery of sensorimotor control.**
- **Postural measures used to quantify changes in the amplitude of performance degradation and/or the time constant(s) of performance recovery**
- **Characterize population demographics as a function of bed rest duration and determining the effects of various countermeasure interventions on sensorimotor control.**



Standard Measures

Functional Fitness (MR078L)

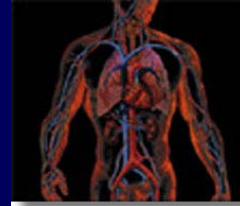
- **Establish baseline skeletal muscle strength, endurance, and flexibility.**
- **Data from bed rest subjects will provide a comparison of bed rest to space flight and a tool for monitoring test subject rehabilitation.**
- **Testing involves standard gym exercises such as sit and reach, Smith bench press, leg press, assisted pull ups, modified push ups, and abdominal crunches.**



Standard Measures

Cardiovascular Assessment Parameters

- Plasma volume and hemodynamic and neuroendocrine responses to tilt.
- Vascular function in the brachial and anterior tibial arteries.
- Flow parameters including resistive index, pulsatility index, acceleration time and velocity time integral.



Standard Measures

Functional Stretch Reflex Test

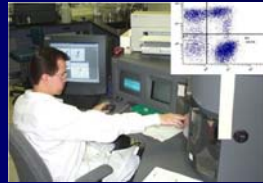
- Assess motor and proprioceptive function in response to bed rest.
- Evaluate otolith sensitivity, kinesthetic and touch receptors, particularly from the bottom of the feet and muscle fiber in the major postural muscles.
- Assess the relationship between signals from visual, vestibular and proprioceptive receptors that could be similar to those changes in motor function that are observed as a function of space flight.
- The goal of this assessment is to test the performance of the major postural muscles (both segmental and central) before, during and after prolonged 6° head down bed rest.



Standard Measures

Immune Function Assessment

- Viral-specific immunity
- Latent virus reactivation
- Physiological stress



Gastrointestinal Function Assessment

- Lactulose / acetaminophen
- Glucose breath test
- Urea breath test



Standard Measures: Future Muscle Measures

- Muscle performance tests will include isometric strength, isometric force control, isotonic power, and isotonic power fatigue.
- All lower body measures will be conducted using an inclined leg press device specifically instrumented for these purposes.
- Lower body measures will be conducted unilaterally such that EMG activity can be directly related to the muscle performance.
- Most functional activities will require that the crewmember support and accelerate his or her body mass on a single limb; few activities are performed with both legs acting together at the same time.
- All upper body measures will be performed bilaterally using a bench press with racking system.



Conclusions

The Bed Rest Project:

- **Represents a significant advancement for investigating the effects of a model of hypogravity on the physiology of the whole body.**
- **Provides a coordinated way to evaluate potential countermeasures for exploration class missions under a controlled environment.**
- **Provides a platform to address NASA's risks for long duration space flight.**
- **Will allow for the examination of possible gender specific effects in response to bed rest.**



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